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**UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF CALIFORNIA**

In re LIDODERM ANTITRUST LITIGATION

Case No. 14-md-02521-WHO

THIS DOCUMENT RELATES TO:  
  
ALL ACTIONS

**PLAINTIFFS' OPPOSITION TO  
DEFENDANTS' REQUEST FOR  
JUDICIAL NOTICE**

Date: November 5, 2014  
Time: 2:00 p.m.  
Courtroom: Courtroom 2, 17th Floor  
Judge: Hon. William H. Orrick

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1 *United States v. Ritchie*,  
2 342 F.3d 903 (9th Cir. 2001) .....2

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4 5A Charles Alan Wright et al., *Federal Practice and Procedure* § 1327  
5 (3d ed. updated April 2014).....2

6 Fed. R. Evid. 201 .....*passim*

## I. INTRODUCTION

Direct Purchaser Plaintiffs, End-Payor Plaintiffs, and GEHA (“Plaintiffs”) oppose Defendants’ Request for Judicial Notice (“RJN”) of materials not contained in or that form the basis of the claims in Plaintiffs’ complaints. *First*, the materials Defendants proffer are not central to Plaintiffs’ claims or extensively referenced in their complaints. *Second*, the purported facts contained in the materials are subject to reasonable dispute. *Third*, Defendants’ request is improper because it asks the Court not only to take notice of the proffered materials, but also impliedly to accept the truth of the matters asserted in the materials.

## II. THE EXTRINSIC MATERIALS

Defendants ask the Court to take judicial notice of the following:

- A. Lidoderm Settlement and License Agreement, entered into between Endo, Teikoku and Watson, dated May 28, 2012 (the “Lidoderm Agreement”).
- B. Watson earnings call transcript for Q3 2011 dated November 1, 2011 (18 pages).
- C. Watson earnings call transcript for Q4 2011 dated February 14, 2012 (18 pages).
- D. Watson earnings call transcript for Q1 2012 dated April 30, 2012 (17 pages).
- E. Endo’s FDA Petition dated December 18, 2006 (23 pages); Endo’s First Amended FDA Petition dated August 29, 2007 (33 pages); and Endo’s Second Amended FDA Petition dated March 12, 2012 (45 pages).

For the Lidoderm Agreement, Defendants note, as is required for judicial notice to be taken, that the document is “central” to Plaintiffs’ claims and “extensively reference[d]” in the complaints.<sup>1</sup> Indeed, this is the Reverse Payment Agreement that forms the basis for many of Plaintiffs’ claims. Plaintiffs welcome the Court’s consideration of any portion of the Lidoderm Agreement.

For the earnings call transcripts, Defendants state the documents are judicially noticeable because they are “publicly available transcripts of earnings calls” and because the complaints purportedly “refer to and quote directly from the Transcripts,” citing one paragraph from each of the

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<sup>1</sup> RJN at 3.

1 DPP and EPP complaints, and nothing from the GEHA complaint.<sup>2</sup> Defendants offer no evidence as  
 2 to whether the content of the transcripts is subject to reasonable dispute.

3 For Endo's FDA petition and two amendments, Defendants state the documents are judicially  
 4 noticeable because they are "available on the [FDA] website" and both the EPP and GEHA  
 5 complaints "cite their contents," noting two paragraphs from the EPP complaint and one paragraph  
 6 from the GEHA complaint, but nothing from the DPP complaint.<sup>3</sup> Defendants offer no evidence as  
 7 to whether the contents of the FDA petition and amendments are subject to reasonable dispute.  
 8 Defendants also fail to disclose that the EPP complaint states that "[o]n August 23, 2012, FDA  
 9 denied Endo's petition in its entirety."<sup>4</sup>

### 10 III. ARGUMENT

11 On a Rule 12(b)(6) motion to dismiss, a Court generally "may not consider any material  
 12 beyond the pleadings."<sup>5</sup> There are two narrow exceptions to this rule. The first applies to documents  
 13 that are "central" to, or form the basis of, the claims in the complaint,<sup>6</sup> or are "extensively  
 14 reference[d]" in the complaint.<sup>7</sup> The second applies to matters of public record, if the information in  
 15 them is "not subject to reasonable dispute."<sup>8</sup> Moreover, "a court can only take judicial notice of the  
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17 <sup>2</sup> *Id.* at 3-4.

18 <sup>3</sup> *Id.*

19 <sup>4</sup> End-Payor Pls.' Consol. Am. Compl. ("EC"), ECF No. 72 (filed June 13, 2014) ¶ 102.

20 <sup>5</sup> *Lee v. City of Los Angeles*, 250 F.3d 668, 688 (9th Cir. 2001) (citation and internal quotation  
 marks omitted).

21 <sup>6</sup> *Kniewel v. ESPN*, 393 F.3d 1068, 1076-77 (9th Cir. 2005) (taking judicial notice of the full set  
 22 of photographs when plaintiff selected a single photograph from the set for attachment to their  
 complaint for defamation); *see In re Immune Response Sec. Litig.*, 375 F. Supp. 2d 983, 995 (S.D.  
 23 Cal. 2005) (in securities class action, rejecting request for judicial notice of documents not  
 24 extensively referenced or necessarily relied upon by plaintiffs, noting that defendants' request would  
 "eliminate the distinction between a motion for summary judgment and a motion to dismiss")  
 (citation omitted).

25 <sup>7</sup> *United States v. Ritchie*, 342 F.3d 903, 907-08 (9th Cir. 2001) (citation and internal quotation  
 marks omitted); *see also* 5A Charles Alan Wright et al., *FEDERAL PRACTICE AND PROCEDURE* § 1327  
 26 (3d ed. updated April 2014) (reference to the existence of a document is insufficient to incorporate  
 the contents of a document into the complaint by reference).

27 <sup>8</sup> Fed. R. Evid. 201(b); *Suzuki Motor Corp. v. Consumers Union of U.S., Inc.*, 330 F.3d 1110,  
 1137 (9th Cir. 2003) (rejecting the proposition that weight should be given to conclusions drawn in  
 28 extrinsic government report).

1 *existence* of those matters of public record . . . but not of the *veracity* of the arguments and disputed  
2 facts contained therein.”<sup>9</sup>

3 As the Ninth Circuit has explained, “[b]ecause the effect of judicial notice is to deprive a  
4 party of an opportunity to use rebuttal evidence, cross-examination, and argument to attack contrary  
5 evidence, caution must be used in determining that a fact is beyond controversy under Rule  
6 201(b).”<sup>10</sup> Accordingly, courts resist taking judicial notice of materials outside the four corners of a  
7 complaint for all but the most ministerial purposes so as to avoid “unforeseen consequences.”<sup>11</sup>

8 **A. The Earnings Reports are Not Central to Plaintiffs’ Claims, and the Contents are**  
9 **Subject to Reasonable Dispute**

10 In describing the anticompetitive effect of the Reverse Payment Agreement and other  
11 anticompetitive conduct by Defendants, DPPs alleged in a single paragraph that

12 Watson told Wall Street analysts in late 2011 and early 2012 that it  
13 was pursuing its ANDA, that it was closely monitoring the progress of  
14 the ANDA and expected approval in 2012, that its efforts to increase  
15 capacity were well underway, and it expected to be “ready to go at the  
16 earliest possible time to launch the product.”<sup>12</sup>

17 The allegation is based on a statement by Paul M. Bisaro, Watson’s President and CEO, drawn from  
18 the Watson earnings call transcript for Q4 2011 dated February 14, 2012.<sup>13</sup> EPPs made a similar  
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20 <sup>9</sup> *Balanced Body Univ., LLC v. Zahourek Sys., Inc.*, 2014 WL 66722, at \*2 (E.D. Cal. Jan. 7,  
21 2014) (quoting *U.S. v. S. Cal. Edison Co.*, 300 F. Supp. 2d 964, 974 (E.D. Cal. 2004)) (emphasis in  
22 original); *see also Cascades Computer Innovation LLC v. RPX Corp.*, No. 12-cv-01143-YGR, 2013  
23 WL 316023, at \*4 n.5 (N.D. Cal. Jan. 24, 2013) (taking judicial notice that certain documents were  
24 filed, and that certain statements were made, but not that the statements contained therein are true).

25 <sup>10</sup> *Rivera v. Philip Morris, Inc.*, 395 F.3d 1142, 1151 (9th Cir. 2005); *see* Fed. R. Evid. 201(g)  
26 (“In a civil proceeding, the court shall instruct the jury to accept as conclusive any fact judicially  
27 noticed.”).

28 <sup>11</sup> *Balanced Body University, LLC v. Zahourek*, 2014 WL 66722, at \*2 (E.D. Cal. Jan. 7, 2014)  
(taking notice of the existence of the docket in related proceedings, but declining to take notice of  
specific documents listed in the docket).

<sup>12</sup> Direct Purchaser Pls.’ Consol. Am. Class Action Compl. (“DC”), ECF No. 70 (filed June 13,  
2014) ¶ 124.

<sup>13</sup> Defendants’ Request for Judicial Notice, Ex. C, Watson earnings call transcript for Q4 2011,  
dated February 14, 2012, at 10. All exhibits referenced herein are to Defendants’ Request for  
Judicial Notice.

1 allegation.<sup>14</sup> As a quotation from the CEO of Watson, the statement is an admission of a party  
 2 opponent and constitutes admissible evidence if offered by Plaintiffs against Defendants.<sup>15</sup>

3 As if this were a motion for summary judgment, or a trial, and not a motion on which the  
 4 Court is required to accept the allegations of material fact in the complaints as true and construe the  
 5 facts in the light most favorable to Plaintiffs,<sup>16</sup> Defendants seek to contest this single fact with three  
 6 separate earnings call transcripts submitted as RJN Exs. B-D.<sup>17</sup> But as the reference to the earnings  
 7 call transcript is made in a single paragraph in two of the three complaints Defendants challenge, and  
 8 references a single sentence in only one transcript, it cannot be said that these materials are  
 9 extensively referenced in the complaints, or central to the allegations. Moreover, despite the heavy  
 10 burden required to prove under Fed. R. Evid. 201(b) that the statements in the earnings call  
 11 transcripts cannot be reasonably questioned, Defendants have come forward with no evidence  
 12 supporting their veracity.<sup>18</sup>

13 Defendants cite *Rosenbaum Capital v. McNulty*<sup>19</sup> to urge that the earnings call transcripts  
 14 deserve judicial notice because they were “publically available and disclosed to the market.” But  
 15 *Rosenbaum* was a securities case that concerned the *existence* of information provided to the market,  
 16 and whether the information was *central* to the case. Defendants also urge notice under the  
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20 <sup>14</sup> EC ¶ 125.

21 <sup>15</sup> *United States v. Arteaga*, 117 F.3d 388, 395 (9th Cir. 1997) (“[U]nder Rule 801(d)(2)(A), a  
 22 party’s own statement, if offered against the party, is not hearsay”); *Arnold v. Pfizer*, 970 F. Supp. 2d  
 23 1106, 1124 (D. Ore. 2013) (statements of employer’s managers qualified for admission as non-  
 24 hearsay as opposing party statements offered against it).

25 <sup>16</sup> *Johnson v. Lucent Techs., Inc.*, 653 F.3d 1000, 1010 (9th Cir. 2011).

26 <sup>17</sup> While Defendants request judicial notice of three earnings call transcripts marked as Exs. B-D,  
 27 their memorandum references only Ex. D. On this basis alone Defendants’ request for judicial notice  
 28 of Exs. B and C should be denied.

<sup>18</sup> See *Newman v. San Joaquin Delta Community Coll. Dist.*, 272 F.R.D. 505, 516 (E.D. Cal. 2011) (“party requesting judicial notice bears the burden of persuading the court that the particular fact is not reasonably subject to dispute”).

<sup>19</sup> 549 F. Supp. 2d 1185, 1189 (N.D. Cal. 2008).



1 incorporation by reference doctrine, citing *Knieval v. ESPN*,<sup>20</sup> but fail to acknowledge that the  
 2 doctrine requires that the proposed material be “‘central’ to the plaintiff’s claim.”<sup>21</sup>

3 Defendants seek judicial notice of the earnings call transcripts to challenge Plaintiffs’  
 4 allegation that Watson would have launched at risk upon FDA approval of Watson’s generic  
 5 Lidoderm ANDA, without waiting for final judgment and dismissal of all potential appeals in the  
 6 patent cases.<sup>22</sup> Defendants would like the Court to review the transcript and conclude that

7 Watson made it clear that it did not expect ANDA approval until the  
 8 Citizen Petition was resolved, and also that it was not going to launch  
 9 at risk. Watson explained that, although it had increased capacity and  
 10 procured raw materials to be in a position to launch generic Lidoderm,  
 11 an actual launch was contingent on FDA approval, over which “there is  
 12 still the Citizen Petition overhang, which sits out there and of course,  
 13 we’re waiting for a trial decision. But we are doing everything we can  
 14 to be ready to go at the earliest possible time.”<sup>23</sup>

15 Defendants are offering the material not only to establish the truth of the matter asserted, but are  
 16 actually asking the Court to find as a matter of law, improperly on a motion to dismiss, that their  
 17 purported interpretation of the material is the *only* plausible reading.

18 Ironically, the statements Defendants cite, as well as other information in the materials,  
 19 actually *support* Plaintiffs’ allegations concerning Watson’s readiness, willingness, and ability to  
 20 launch at risk.

21 *First*, Watson’s CEO Paul Bisaro unequivocally references “a trial decision,” which is  
 22 referring to a single trial – the February 2012 bench trial in the District of Delaware on U.S. Patent  
 23 No. 5,827,529, a decision for which was expected imminently. This undermines Defendants’  
 24 implication that Watson was waiting for an appeal of any decision in that trial, or for an outcome  
 25 from the other litigation that Endo had filed over the other patents it had obtained and listed in the  
 26 Orange Book as covering Lidoderm.<sup>24</sup>

27 <sup>20</sup> 393 F.3d 1068 (9th Cir. 2005).

28 <sup>21</sup> *Id.*; see n.6, *supra*.

<sup>22</sup> Defendants’ Motion to Dismiss Mem. at 22-23.

<sup>23</sup> Defendants’ Mem. at 23 (quoting RJN Ex. D, Q1, 2012 Earnings Call Transcript).

<sup>24</sup> Ex. C at 7.

1           *Second*, Mr. Bisaro unequivocally stated that Watson intended to be ready to launch “at the  
2 earliest possible time,” which would be upon FDA approval. That is the “earliest possible time” that  
3 Watson could launch. In this case, that date was August 23, 2012.<sup>25</sup>

4           *Third*, as early as Watson’s earnings call for Q3 2011 on November 1, 2011, Mr. Bisaro was  
5 reporting that “[w]e like our case, we like where our case sits. We think we’ve, the District Court  
6 has been certainly in the Markman hearing was, we think was favorable to us and we’re pretty  
7 excited about where that product opportunity presents itself.”<sup>26</sup>

8           *Fourth*, on multiple occasions, Mr. Bisaro stated that Watson remained “focused on trying to  
9 win at trial and getting prepared for launch” and “doing everything we can to be ready to go at the  
10 earliest possible time.”<sup>27</sup>

11           *Fifth*, when asked by an independent analyst directly whether Watson would launch at risk,  
12 Mr. Bisaro answered confidently, stating:

13                   <Q – **John T. Boris**>: . . . And Paul, if you do win, which it seems as  
14 though there is a pretty high probability you will prevail in this trial,  
would you launch at risk or wait until after an appeal had occurred?

15                   <A – **Paul M. Bisaro**>: Well, John, I think you probably know me  
16 well enough to know that if we remove all barriers, we would probably  
consider that a very high probability getting out with this product.<sup>28</sup>

17           At bottom, Defendants’ request for judicial notice of the earnings call transcripts is  
18 objectionable on substance because it seeks to have the Court draw meaning from the materials and  
19 make findings that may bind the parties, without the benefit of a record based on full discovery of  
20 Defendants’ documents and examination of its witnesses. On this motion, Defendants’ challenge to  
21 Plaintiffs’ claim must be limited to the allegations in Plaintiffs’ complaints. The Watson earnings  
22 call transcripts may not be considered.

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25           <sup>25</sup> *Id.*

26           <sup>26</sup> Ex. B at 8.

27           <sup>27</sup> Ex. C at 8 and Ex. D at 7.

28           <sup>28</sup> Ex. C at 15.

**B. The FDA Petition and Amendments are Not Central to Plaintiffs' Claims, and the Contents are Not Subject to Reasonable Dispute**

In setting out the chronology leading to the Reverse Payment Agreement and its execution, the EPP and GEHA complaints refer to Endo's FDA petition and amendments concerning testing standards for generic Lidoderm.<sup>29</sup> Endo's petition purported to challenge the effectiveness of FDA's test protocols for determining the bioequivalence of proposed generic Lidoderm formulations. Endo claimed that FDA's test standard raised "[s]afety concerns" and has "implications on safety, effectiveness, and consumer trust."<sup>30</sup>

Seeking to misdirect the Court away from the unreasonable restraint on competition imposed by the Reverse Payment Agreement, and to claim real uncertainty by Watson as to whether its generic Lidoderm ANDA would be approved, Defendants seize on this incidental reference to place before the Court Endo's three FDA petition submissions totaling over 100 pages,<sup>31</sup> and to then reference Endo's FDA petition filings in their memorandum no fewer than 25 times. But as the reference to the FDA petitions is made only briefly, and in only two of the three complaints, these materials cannot be said to be extensively referenced by Plaintiffs or central to their claims. Moreover, the substance of the materials is subject to more than reasonable dispute. After all, the FDA rejected Endo's requests in their entirety.

Defendants cite *Gustavson v. Wrigley Sales Co.*<sup>32</sup> to argue that the Court may take judicial notice of Endo's FDA submissions because they are available on a government agency website. But there, the court took judicial notice of documents issued by the *government* on government websites, not advocacy pieces by private parties that were posted on government websites.<sup>33</sup> Similarly, in *Novartis Pharm. Corp. v. Wockhardt USA LLC*,<sup>34</sup> upon which Defendants also rely, the Court took

<sup>29</sup> See EC ¶¶ 101-02; Gov't Employees Health Ass'n First Am. Compl. ("GC"), ECF No. 71 (filed June 13, 2014) ¶ 6.

<sup>30</sup> Ex. E, Endo's FDA Petition dated December 18, 2006, at 14 and 22.

<sup>31</sup> RJN Ex. E.

<sup>32</sup> 961 F. Supp. 2d 1100, 1113 n.1 (N.D. Cal. 2013)

<sup>33</sup> *Id.*, identifying FDA guidance documents, an amicus brief filed by the Solicitor General's Office, and a table listing the names and citations of other cases concerning the same subject matter.

<sup>34</sup> 2013 WL 5770539, at \*1 (D.N.J. Oct. 23, 2013).

1 judicial notice of *FDA's response* to a petition, not a party's petition itself. Notably, Defendants here  
 2 do not ask the Court to take notice of the FDA's response denying the requests in their FDA filings.

3 Plaintiffs do not dispute that Endo filed FDA petitions, or that the petitions were denied in  
 4 their entirety on August 23, 2012, the date that FDA granted Final Approval to Watson's generic  
 5 Lidoderm ANDA, and the date that Plaintiffs allege Watson would have launched generic Lidoderm  
 6 but for the Reverse Payment Agreement. But Defendants seek judicial notice of Endo's FDA  
 7 petition filings not to prove the existence of the filings, but to have the Court accept unchallenged the  
 8 substance of the claims in the petition and to draw inferences about how Watson perceived the  
 9 impact of the petitions on the launch of its generic.<sup>35</sup>

10 While Plaintiffs contend that Defendants' request for judicial notice is improper, were the  
 11 Court to allow Defendants' request, Plaintiffs would note the substantial evidence in the earnings call  
 12 transcripts that Watson did not believe Endo's petition filings had a reasonable chance of blocking  
 13 FDA approval of its generic Lidoderm ANDA. In particular, as early as Watson's earnings call for  
 14 Q3 2011 on November 1, 2011, Mr. Bisaro was telling financial analysts that Watson believed  
 15 Endo's FDA petition would be denied, explaining that "the FDA has already given guidance on this  
 16 issue and we have followed that guidance. And we don't believe we're going to be required to do  
 17 any more work than what we've already done."<sup>36</sup> Mr. Bisaro underscored Watson's view during  
 18 Watson's earnings call for Q4 2011 on February 14, 2012, when he reiterated that

19 [T]he FDA has been very clear about patch products. We believe that  
 20 patches don't require that kind of clinical endpoint study, what it  
 requires is the studies that we've performed per the guidance that they

21 <sup>35</sup> In *In re Niaspan Antitrust Litig.*, No. 2:13-md-2460 (E.D. Pa. Sept. 8, 2014), ECF No. 112 at  
 22 25-26, the court rejected defendant's attempt on motion to dismiss in reverse payment case to have  
 the court take judicial notice of "'historical facts concerning the [underlying] patent litigation,'" reasoning that

23 [a]lthough a court may take judicial notice of court documents to establish the fact  
 24 of the litigation or of the filings themselves . . . in this case, defendants ask the  
 25 Court to find a fact in dispute based on these documents, namely [defendant's]  
 chances of prevailing in the underlying litigation. This is a plainly improper use of  
 26 the doctrine.

27 (Citations omitted).

28 <sup>36</sup> RJN Ex. B at 8.

1 issued. . . . So I don't understand why the FDA would go back and  
2 change their mind on this when they were that clear when they were  
asked through the citizen's petition process.<sup>37</sup>

3 Plaintiffs would also note Endo's and Teikoku's insincerity in claiming their petition filings  
4 were motivated by concern for safety of consumers, given that Endo and Teikoku willingly agreed  
5 with Watson that Endo would not make any additional supportive petition filings in exchange for  
6 Watson's agreement to perpetuate Endo and Teikoku's Lidoderm monopoly through the Reverse  
7 Payment Agreement, at the expense of these very consumers.

8 But Plaintiffs do not make that argument here. Endo's FDA filings are an improper subject  
9 of judicial notice.

#### 10 IV. CONCLUSION

11 For the reasons stated above, this Court should deny Defendants' request for judicial notice.  
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28 <sup>37</sup> *Id.* Ex. C at 17.

1 Dated: September 8, 2014

2 Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I hereby certify that on September 8, 2014, I electronically filed the foregoing document using the CM/ECF system which will send notification of such filing to the e-mail addresses registered in the CM/ECF system, as denoted on the Electronic Mail Notice List, and I hereby certify that I have caused to be mailed a paper copy of the foregoing document via the United States Postal Service to the non-CM/ECF participants indicated on the Manual Notice List generated by the CM/ECF system.

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